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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,383	12/29/2004	Alain Sanson	263864U/SOX PCT	6816
22850 7590 09/17/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER GUPTA, ANISH				
ART UNIT 1654		PAPER NUMBER		
NOTIFICATION DATE 09/17/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/518,383

Applicant(s)

SANSON ET AL.

Examiner

ANISH GUPTA

Art Unit

1654

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-62 is/are pending in the application.
- 4a) Of the above claim(s) 10-14, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 4-5, 8-9, 36-39 is/are allowed.
- 6) ☐ Claim(s) 2, 6, 7, 15, 16, 19-35 and 40-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-08-09 has been entered.

Election/Restrictions

2. Applicant's election of Group I, claims 1-9, 15-16, and 19-61 in the reply filed on 2-11-08 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Applicants also elected the species of SEQ ID NO 1, without any labels. A search was done for SEQ ID NO 1, and it was found to be free of the prior art. Search was extended to SEQ ID NO 2-14 and they too were found to be free of the prior art. In accordance Markush practice, the search was extended to the peptide of SEQ ID 15 of claim 1. This too was free of the prior art. Thus claims 1-9, 15-16 and 19-61 have been examined.

Claims 10-14, 17-18 have been withdrawn from consideration as corresponding to non elected Group.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 6-7, 15-16, 19-35, 40-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended from J represents amino acids to all the J variables defined by specific amino acids. Thus, now J26 is defined as Leu, Val or Ile, J64 as Phe, Leu or Met, etc. . . New claim defines all of the J variables with specific amino acids in each J variable position. This amendment to the claims constitutes new matter.

Lack of Literal Support

The originally filed disclosure discloses J an natural amino aids, “in such a manner that at least 50% of them are polar residues chosen from Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, and Tyr (see page 11). Furthermore, the specification state that all J's can be chosen from Ala, Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Ile, Leu, Lys, Met, Orn, PHe, Pro, Ser, Thr, Trp, Tyr, and Val (see page 15 of the specification). However the specification does not specifically recite that J 26, for example, is only Leu, Val, Ile. There is no literal support for the specific J variables as claimed in claim 1 and new claim 30. Furthermore, the originally file disclosure requires the presence of J36. However, the claims do not contain the variable J36 in the sequence. The specification does not provide any support to delete variable J36.

Lack of Inherent Support

“While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” MPEP 2163. The originally filed

disclosure does not provide either implicit or inherent support for the new limitations. There is no guidance within the specification that J variable have specific amino acid substitutions as now currently claimed. The specification generally teaches that J variables are surface amino acids or residues of this peptide when it is in the folded and active conformation. However this does not lead on of ordinary skill in the art to envision that J are very specific residues as currently claimed. The specification only describes the J's in a general manner without any specificity with respect specific amino acid at any given J position.

The specific example and species also do not provide any implicit or inherent support for the markush for the J variables as now claimed. The specification discloses fourteen specific amino acid sequences. These fourteen amino acid sequences do not adequately represent the variability of the claimed genus. For example, the claimed invention states that variable J74 can be Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, Tyr. However, the none of the examples have amino acids that contain a Cys, Lys, Pro or Orn, for example, in position J74. This is also true of other positions within the markush. Furthermore, the species do not provide support for all of the differing combinations of the J variables. There are no species that have Orn in more than one J position. For that matter, there are no species that contain a single Orn residue in any position. Thus, the claims for provide implicit support for the new markush group. Furthermore, there is no support for the deletion of the variable J36 within the sequence. The newly added markush requires that J36 not be present within the sequence. However, all of the species require the presence of an amino acid corresponding to J36.

New Grounds For Rejections

Claim Rejections - 35 USC § 112

Art Unit: 1654

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 6-7, 15-16, 19-35, 40-62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62 recites variable J36 as Gln or GLu in sequence (I'). However, J36i s not present in the sequence (I'). It is unclear if J36 should be required in the sequences.

5. Claims 4-5, 8-9, 36-39 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654